

REMARKSClaim Status

Claims 1-17, 19-33, 37 and 38 are pending in this application and stand rejected. Reconsideration in view of the following remarks is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-17, 19-33, 37 and 38 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over WO 98/34,644, for reasons of record, in view of Chen (U.S. 6,602,274). Briefly, WO 98/34644 is said to disclose that low dose PDT can be used to reduce inflammation in injured or pre-injured tissues, where the Office takes the position that tissues that overlap with the tissues treated with normal dose PDT are “pre-injured” tissues. Chen is said to disclose that PDT causes damage to normal tissues beyond the treated area. Applicants traverse the rejections for reasons of record, as well as at least the following reasons.

With regard to the comments regarding the enablement of *preventing* inflammation, the Applicants note that the claims are not drawn to methods for *preventing* inflammation, but to methods for reducing or treating inflammation cause by normal dose PDT in a tissue area exposed to normal dose PDT.

The Examiner states that WO 98/34644 shows that inflammation can be treated or reduced by low dose PDT. Chen is relied upon to show “the effect of photodynamic therapy on the tissues beyond the treated area and damage caused to such tissues by such treatment” (Office action, page 2). The Examiner concludes that it would have been obvious to one of skill in the art to use low dose PDT to treat inflammation caused by any source. The Applicants respectfully disagree.

Chen states in relevant part that: “[a]ny photosensitizer absorbed by normal tissue in the path of the beam will likely be activated and cause unwanted collateral normal tissue damage.” See Chen, at col. 2, lines 36-38 (emphasis added). Thus, the “normal tissue” that is damaged in Chen is tissue in the path of the beam, i.e., tissue that has been irradiated using normal dose PDT.

Applicants respectfully submit that tissue in the path of the beam constitutes treated tissue. Thus, Chen cannot be taken to suggest that normal dose PDT results in inflammation in adjacent tissue regions that are not exposed to photoactivating light and so not exposed to normal dose PDT. Accordingly, Chen is clearly distinguishable from the invention as claimed, which relates to low dose PDT treatment of tissue areas which were previously untreated with photoactivating light (such as in normal dose PDT).

In view of the foregoing remarks, the Applicants respectfully submit that the cited art, alone or in combination, fails to disclose or otherwise suggest that normal dose PDT results in inflammation in adjacent or overlapping tissue areas that were not exposed to normal dose PDT.

The Applicants respectfully disagree with the characterization that the Applicants have acknowledged a need for reduction and prevention of inflammation caused by normal dose PDT (Office action at page 3). As stated in the Applicant's response filed June 18, 2009, there is no teaching or suggestion in the cited documents that, as a general rule, inflammation caused by PDT should be treated or reduced. As evidenced by both Freitas (already of record) and WO 98/34644 (page 15, lines 18-25), it was recognized in the art that inflammation associated with normal dose PDT could be *desirable* under certain circumstances, including, e.g., the treatment of tumors. One of skill in the art would not consider reduction or prevention of inflammation to be either needed or desirable in such cases.

The Examiner disregards the disclosure of Freitas, published in 1991, that inflammation associated with normal dose PDT may be desirable in some circumstances, and asserts that in view of the later-published WO 98/34644, one of skill in the art would recognize a need to reduce inflammation caused by normal dose PDT. Although inflammation caused by the "potentially destructive, necrotic effect of PDT" in some contexts is disclosed in WO 98/34644 (page 16, lines 18-21), nothing in this document suggests that low dose PDT can be used to treat such inflammation, in contrast to the treatment of inflammation caused by physical or chemical agents, as described in the cited reference.

Moreover, there is no basis to conclude that one of skill in the art would disregard Freitas in view of WO 98/34644, which includes potentially conflicting information regarding inflammation associated with normal dose PDT. At best, the existence of conflicting information in the art cited by the Office would leave one of skill in the art without clear guidance as to whether inflammation should be reduced or not.

Assuming solely for the sake of argument that one of skill in the art was motivated to reduce inflammation caused by normal dose PDT in a particular context, the Applicants respectfully submit that one of skill in the art would not have had a reasonable expectation that low dose PDT could be used to reduce or treat such inflammation. In addition, the Examiner had pointed to nothing in the cited art that discloses or otherwise suggests exposing an overlapping tissue area that is concentric with but larger than the area previously exposed to normal dose PDT.

Applicants submit that a *prima facie* case of obviousness has not been established. Accordingly, the rejections under 35 U.S.C. § 103(a) should be withdrawn.

Evidence of unexpected results rebuts any *prima facie* case of obviousness

Applicants respectfully submit that as no *prima facie* case has been provided, the Applicants have no burden to submit rebuttal evidence. Nevertheless, Applicants respectfully submit that the fact that low dose PDT can be successfully used to reduce inflammation caused by normal dose PDT is itself an unexpected result, for reasons of record. The Office has provided no reasonable expectation in the field that following a first exposure to normal dose PDT that causes acute inflammation, additional treatment with PDT would result in a reduction or treatment of the inflammation.

In view of the foregoing remarks, Applicants respectfully request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 273012011800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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